IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8434

Bartle, C.J. March 17, 2010

Janet Gladwin ("Ms. Gladwin" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Arnold B. Meshkov, M.D., F.A.C.C. Based on an echocardiogram dated June 6, 2001, Dr. Meshkov attested in Part II of Ms. Gladwin's Green Form that she suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[3] Based on

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Meshkov also attested that claimant suffered from bacterial endocarditis, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $787,730.[4]

In the report of claimant's echocardiogram, the reviewing cardiologist stated that the echocardiogram revealed a "[m]yxomatous mitral valve with posterior leaflet prolapse: moderate vegetation (6-7mm) seen on posterior leaflet with possible vegetation on anterior leaflet." Mitral valve prolapse is defined in the Settlement Agreement as a condition where:

> (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

Settlement Agreement § I.39. Under the Settlement Agreement, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)b). As the Trust does not contest Ms. Gladwin's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In May, 2005, the Trust forwarded the claim for review by Ernest C. Madu, M.D., F.A.C.C., F.A.C.P., F.C.C.P., one of its

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4. Under the Settlement Agreement, a claimant is entitled to Level III benefits for damage to the mitral valve if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement IV.B.2.c.(3)(a).

auditing cardiologists.[5] In audit, Dr. Madu concluded that there was no reasonable medical basis for Dr. Meshkov's finding that claimant did not have mitral valve prolapse. In support of this conclusion, Dr. Madu explained that the "[e]chocardiogram shows definite prolapse."

Based on the auditing cardiologist's finding that claimant had mitral valve prolapse, the Trust issued a post-audit determination that Ms. Gladwin was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that Dr. Madu's opinion that the "echocardiogram shows definite prolapse" was insufficient to deny Matrix A-1 benefits. Additionally, claimant submitted a supplemental report from Dr. Meshkov, in which he stated:

> The anatomic and pathologic findings of this echo Doppler study are consistent with damage to portions of both the anterior and posterior mitral valve leaflets due to Ms. Gladwin's history of bacterial endocarditis.

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5. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims are subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that Ms. Gladwin had a Matrix A-1, Level V claim, pursuant to the PPP, the Trust audited Ms. Gladwin's claim.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Gladwin's claim.

> The anterior and posterior leaflets of the mitral valve have three separate scallops or portions of the leaflets. On the long axis view there is displacement of one of the scallops of the anterior leaflet and one of the scallops of the posterior leaflet greater than 2 mm above the atrial ventricular border during systole. However this displacement does not involve 2 of the 3 scallops of both the anterior and posterior leaflets. There is greater than 5 mm thickening again of only the diseased portions of the anterior and posterior leaflet during diastole.
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> The findings of this echo Doppler study are not consistent with the findings of mitral valve prolapse as defined by the Settlement Agreement. The Settlement Agreement indicates that there is a requirement of displacement of "1 or both mitral leaflets over 2 mm above the atrial-ventricular border during systole." In this particular case the pathologic changes caused by endocarditis resulted in displacement of only 1 scallop of the 3 of both the anterior and posterior mitral valve leaflets. This type of pathology is clearly not the same as that seen with mitral valve prolapse, where there is a generalized, longstanding myxomatous degenerative process involving one or both of the mitral valve leaflets resulting in displacement of the anterior or posterior leaflets, or both leaflets, in their entirety, above the atrial-ventricular border during systole. It is also important to note that at the time of surgical removal of the mitral valve, the anatomic findings by the surgeon were that the damage to the mitral valve was localized and caused only by the previous bacterial endocarditis infection. There was no evidence of myxomatous degeneration that would predispose to mitral valve prolapse.

The Trust then issued a final post-audit determination, again determining that Ms. Gladwin was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Gladwin's claim should be paid. On January 12, 2006 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 6, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have mitral valve prolapse. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Gladwin argues that: (1) Dr. Meshkov found only one portion of the leaflets was displaced, and the Settlement Agreement requires that the leaflet itself be displaced in order to make a finding of mitral valve prolapse; (2) Dr. Madu does not comment on whether the entirety of either leaflet was displaced; and (3) Dr. Meshkov found that the displacement of the portion of the leaflet was caused by endocarditis, and not by a generalized, long-standing myxomatous degenerative process, which is supported by claimant's operative report.

In response, the Trust argues that neither the Settlement Agreement nor the Green Form requires that the entirety of the mitral valve leaflet be displaced in order to establish the presence of mitral valve prolapse. The Trust also

asserts that, based on Dr. Meshkov's own findings, claimant has mitral valve prolapse as defined by the Settlement Agreement. Finally, the Trust contends that the cause of claimant's mitral valve prolapse is irrelevant to her claim for Matrix Benefits.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding that Ms. Gladwin did not have mitral valve prolapse. Specifically, Dr. Vigilante found that:

> On the parasternal long-axis view, there was obvious prolapse of the anterior mitral leaflet with partial flailing of A-2 scallop. The anterior leaflet was displaced 4 mm above the atrial-ventricular border in this view. In addition, the anterior leaflet was 7 mm thick during diastole in the parasternal long-axis view. Furthermore, there was a moderate sized vegetation associated with the anterior mitral leaflet. The posterior mitral leaflet was also thickened and vegetation was noted on the atrial side towards the base of this leaflet .... Without question, this study meets the Settlement Agreement criteria for mitral valve prolapse regarding the displacement of the mitral leaflet in systole and leaflet thickening during diastole. It should be noted that mitral valve prolapse frequently involves only one of the mitral leaflet scallops.

In response to the Technical Advisor Report, claimant reasserts her previous arguments. In addition, claimant contends that Dr. Vigilante's opinion should not be adopted by the court because Dr. Vigilante failed to cite any medical literature indicating that Dr. Meshkov's opinion lacks a reasonable medical basis.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Significantly, Dr. Meshkov, claimant's attesting physician, acknowledges that claimant's echocardiogram reveals mitral valve prolapse as defined by the Settlement Agreement. As stated previously, mitral valve prolapse is defined as a condition where:

> (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.

See Settlement Agreement § I.39. Specifically, in his August 29, 2005 letter in support of claimant's contest, Dr. Meshkov found that:

> On the long axis view there is displacement of one of the scallops of the anterior leaflet and one of the scallops of the posterior leaflet greater than 2 mm above the atrial ventricular border during systole .... There is greater than 5 mm thickening again of only the diseased portions of the anterior and posterior leaflet during diastole.

Dr. Vigilante, moreover, determined that claimant had mitral valve prolapse. Specifically, Dr. Vigilante found that "[t]he anterior leaflet was displaced 4 mm above the atrial-ventricular border" and that "the anterior leaflet was 7 mm thick during diastole." On this basis alone, claimant has failed to meet her burden of demonstrating a reasonable medical basis for her claim.

We also reject claimant's argument that the presence of mitral valve prolapse as defined in the Settlement Agreement is not sufficient to reduce a claim to Matrix B-1 unless the entire leaflet itself is displaced. At the outset, nothing in the Settlement Agreement's definition of mitral valve prolapse suggests that, notwithstanding the presence of mitral valve prolapse, a claimant may nevertheless receive Matrix A-1 benefits by simply asserting that his or her mitral valve prolapse is limited to only a portion of a mitral valve leaflet. Indeed, such an interpretation would be inconsistent with the intent of the Settlement Agreement, which requires the payment of reduced Matrix Benefits if certain conditions are demonstrated by claimant's echocardiogram or medical records. As claimant's own expert concedes that claimant has mitral valve prolapse, as specifically defined by the Settlement Agreement, Ms. Gladwin's claim must be reduced to Matrix B-1. Additionally, the Technical Advisor, Dr. Vigilante, noted that "mitral valve prolapse frequently involves only one of the mitral leaflet scallops," i.e., a portion of the leaflet. For these reasons, we find that requiring the entire leaflet to be displaced for application of the reduction factor of mitral valve prolapse would be inconsistent with the intent of the Settlement Agreement.

Finally, claimant's argument that the displacement and thickening of her mitral valve leaflets was caused by endocarditis, and not by a generalized, long-standing myxomatous degenerative process is irrelevant. Causation is not at issue in

resolving Ms. Gladwin's claim for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred ....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation or valve replacement at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if claimant's echocardiogram reveals evidence of mitral valve prolapse, and we must apply the Settlement Agreement as written. Accordingly, claimant's assertion that the cause of her mitral valve prolapse was endocarditis is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral valve prolapse. Therefore, we will affirm the Trust's denial of Ms. Gladwin's claim for Matrix A-1 benefits.